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Risk Reduction and Environmental Stewardship— Environmental Characterization and Remediation

**Quality Procedure** 

for Analytical Data Verification/
Validation Process

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# **Revision Log**

Revision No.	Effective Date	Prepared By	Description of Changes	Affected Pages
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# **Analytical Data Verification/Validation Process**

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## **List of Acronyms and Abbreviations**

LANL	Los Alamos National Laboratory
QP	Quality Procedure
QPPL	Quality Program Project Leader
RRES-RS	Risk Reduction and Environmental Stewardship—Remediation Services

RRES-ECR Risk Reduction and Environmental Stewardship—Environmental Characterization and Remediation

Sample Management Office

SMO SOP Standard Operating Procedure

## **Analytical Data Verification/Validation Process**

#### 1.0 PURPOSE

This quality procedure (QP) states the responsibilities and describes the process for verifying and validating analytical data within the Los Alamos National Laboratory (LANL or the Laboratory) Risk Reduction and Environmental Stewardship Division (RRES) the Environmental Characterization and Remediation (ECR) Group. This procedure integrates the criteria of the "Risk Reduction and Environmental Stewardship – Remediation Services Project Quality Management Plan," hereinafter referred to as the "Quality Management Plan."

#### 2.0 SCOPE

- 2.1 All **ECR participants** shall implement this QP when verifying and validating analytical data for the RRES-RS/ECR Project.
- 2.2 **Subcontractors** performing work under the RRES-RS/ECR project quality program shall follow this QP.

#### 3.0 TRAINING

- 3.1 **ECR participants** shall train to and use the current version of this QP; contact the author of this QP if the text is unclear.
- 3.2 **ECR participants** using this QP shall document training in accordance with QP-2.2.
- 3.3 The responsible **project leader (PL)** shall monitor the proper implementation of this procedure.
- 3.4 The responsible **team leader (TL)** shall ensure that the appropriate personnel complete all applicable training assignments.
- 3.5 **ECR participants** may request any needed assistance with implementation of this procedure from RRES-RS Quality Integration and Improvement (QII).

#### 4.0 **DEFINITIONS**

4.1 Data validation—A systematic process that applies a defined set of performance-based criteria to a body of data; may result in qualification of the data. The data validation process is performed independently of the analytical laboratory that generates the data set and occurs before conclusions are drawn from the data. The process may comprise a standardized data review (routine data validation) and/or a problem-

- specific data review *(focused data validation)*. A chemist performs validation.
- 4.2 Data verification—A process of evaluating the completeness, correctness, consistency, and compliance of a laboratory data package against a specified standard or contract.
  - Completeness means all required information is present—both hard copy and electronic.
  - Correctness means the reported results are based on properly documented and correctly applied algorithms.
  - Consistency means values are the same when they appear in different reports or transcribed from one report to another.
  - Compliance means the data pass numerical quality control (QC) tests based on parameters or limits specified in a contract or in an auxiliary document.

#### 5.0 RESPONSIBLE PERSONNEL

The following personnel are responsible for activities identified in this procedure:

- Data validator
- Data verifier
- Project leader
- Quality program project leader
- ECR participants
- Team leader

#### 6.0 PROCEDURE

Attachment A, Analytical Data Verification/Validation Process Flow Chart, symbolizes a pictorial representation of the following process.

6.1 Perform Data Verification

The **data verifier** shall perform the following process steps after receiving an analytical-data package Form I from the Sample Management Office (SMO).

- 6.1.1 Open verification/validation module on the RRES-RS intranet.
- 6.1.2 Select "List" under "Verification."
- 6.1.3 Select a request number.

- 6.1.4 Within an opened request number, select a specific analytical suite.
- 6.1.5 Select "Form 1" button that opens Form 1 Report view.
- 6.1.6 Verify Form 1 hardcopy with Electronic Form 1.
- 6.1.7 If hardcopy and electronic-data match or not, perform the following:
  - 6.1.7.1 If match, select "Accepted" in "Verification Status Field."
  - 6.1.7.2 Select "Save" button.
  - 6.1.7.3 If data do not match, select appropriate verification status in "Verification Status" field.
  - 6.1.7.4 If verifier selects "In Process" status, may continue work process later.
  - 6.1.7.5 If verifier selects "Problem" or "Rejected" status,
    - fill in appropriate comments;
    - select "E-Mail Problem" button;
    - select "Save" button;
    - appropriate personnel will fix problem; and
    - Request Number/Analytical Suite "kicked back" to "Verification List" in order to complete verification; repeat from section 6.1.3 above.
- 6.1.8 If the verification of request number is not complete, repeat from section 6.1.4 above.
- 6.1.9 If the verification of request number is complete, proceed to section 6.2 below.
- 6.2 Perform Data Validation

The **validator** shall perform the following steps:

- 6.2.1 Select "list" under "Validation."
- 6.2.2 Select "Request Number."
- 6.2.3 Select Analytical Suite.
- 6.2.4 Select "Qualifier Reasons" button.
- 6.2.5 Select validation qualifier/reason code, guidance in SOPs-15.01 through -15.07, as applicable, per "Analytical Suite Type."

- 6.2.6 Select "Final Reporting Qualifier/Reason Code" button.
- 6.2.7 Complete qualifier/reason code entry for each analytical suite.
- 6.2.8 Determine "Validation Status."
  - 6.2.8.1 If the "Validation Status" is complete,
    - select "Complete" in "Validation Status" field; and
    - select "Save" button.
  - 6.2.8.2 If the "Validation Status" is not complete, select appropriate validation in "Validation Status" field.
  - 6.2.8.3 If Validator selects "Problem" or "Rejected" status,
    - fill in appropriate comments;
    - select "E-Mail Problem" button;
    - select "Save" button;
    - appropriate personnel will fix problem; and
    - Request Number/Analytical Suite "kicked back" to "Validation List" in order to complete validation; repeat from section 6.2.2.
- 6.2.9 If validation of request number is not complete, repeat from section 6.2.3.
- 6.2.10 If validation of request number is complete, proceed to section 6.3.
- 6.3 Perform Validation Check

The **verifier** shall perform the following steps.

- 6.3.1 Select "List" under "Validation Check."
- 6.3.2 Select "Request Number."
- 6.3.3 Select "Analytical Suite."
- 6.3.4 Select "Form 1" button.
- 6.3.5 Verify Electronic Qualifier Reason Code against hardcopy Validation Form 1 Report.
- 6.3.6 If match.
  - select "complete" in the "Verification Status Field"; and
  - select "Save" Button.

- 6.3.6.1 If validation check is complete,
  - select "List" under "Upload";
  - select "Request Number";
  - select "Analytical Suite" and
  - select "Load to CAR."
- 6.3.6.2 If validation check is not complete, return to and repeat from section 6.3.3.
- 6.3.7 If Electronic Qualifier Reason Code and hardcopy Validation Form 1 Report do not match, select appropriate status in "Verification Status" field.
  - 6.3.7.1 If Validator selects "In Process," may continue work process later.
  - 6.3.7.2 If "In Process" is not selected
    - select "Problem" or "Rejected" status;
    - fill in appropriate comments;
    - select "E-Mail Problem" button:
    - select "Save" button;
    - appropriate personnel will fix problem; and
    - Request Number/Analytical Suite "kicked back" to "Validation Check"; repeat from section 6.3.2.

#### 7.0 LESSONS LEARNED

- 7.1 Before performing work described in this QP, RRES-RS/ECR Project participants should go to the Department of Energy Lessons Learned Information Services home page, located at http://www.tis.eh.doe.gov/ll/ll.html, and/or to the LANL Lessons Learned Resources web page, located at http://www.lanl.gov/projects/lessons\_learned/, and search for applicable lessons.
- 7.2 During work performance and/or after the completion of work activities, RRES-RS/ECR Project participants, as appropriate, shall identify, document, and submit lessons learned in accordance with the LANL,

Lessons Learned System located at http://www.lanl.gov/projects/lessons learned/.

#### 8.0 RECORDS

No records generated from this QP.

#### 9.0 REFERENCES

To implement properly this QP, RRES-RS/ECR Project participants should become familiar with the contents of the following documents, located at <a href="http://erinternal.lanl.gov/home\_links/Library\_proc.shtml">http://erinternal.lanl.gov/home\_links/Library\_proc.shtml</a>:

- "Quality Management Plan"
- QP-2.2, "Personnel Training Management"
- QP-4.4, "Record Transmittal to the Records Processing Facility"
- SOP-15.01, Rev. 1, "Routine Validation of Volatile Organic Data"
- SOP-15.02, Rev. 1, "Routine Validation of Semivolatile Organic Data"
- SOP-15.03, Rev. 1, "Routine Validation of Organochlorine Pesticides and Polychlorinated Biphenyls Data"
- SOP-15.04, Rev. 1, "Routine Validation of High Explosives Data"
- SOP-15.05, Rev. 1, ICN 1, "Routine Validation of Inorganic Data"
- SOP-15.06, Rev. 1, ICN 1, "Routine Validation of Gamma Spectroscopy Data"
- SOP-15.07, Rev. 1, ICN 1, "Routine Validation of Chemical Separation Alpha Spectrometry, Gas Proportional Counting, and Liquid Scintillation Data"

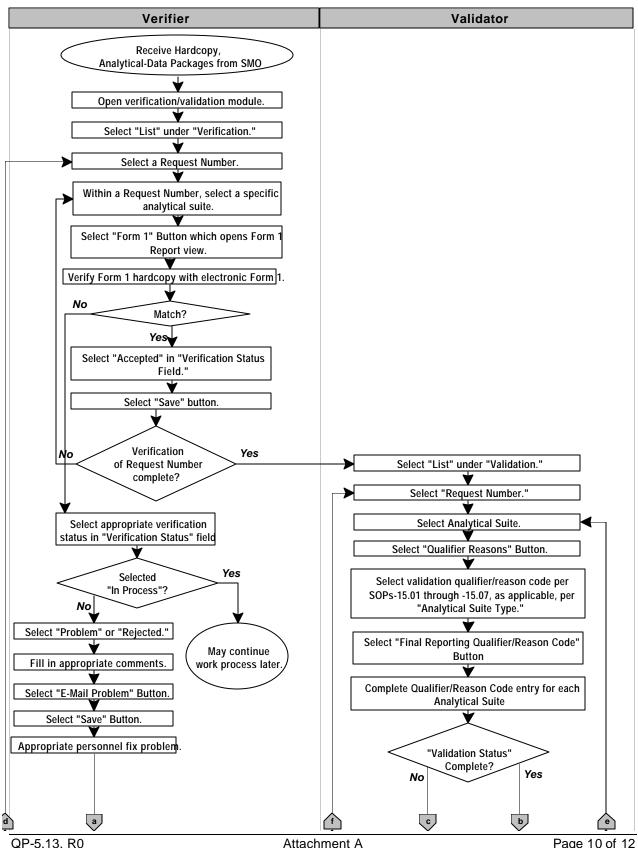
#### **10.0 ATTACHMENTS**

• Attachment A: Analytical Data Verification/Validation Process Flow Chart

<u>Using a token card, click here to record "self-study" training to this procedure.</u>

If you do not possess a token card or encounter problems, contact the RRES-ECR training specialist.

## Attachment A: Analytical Data Verification/Validation Process Flow Chart



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Attachment A

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# Attachment A: Analytical Data Verification/Validation Process Flow Chart

